

Application Serial No. 10/554,290
Request for Reconsideration dated 8 September 2009
Reply to Office Action dated 11 June 2009

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. (Previously Presented) A pharmaceutical composition comprising:
 - a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of equal to or less than 0.2 μm , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities, and
 - a botanical extract, or a pharmaceutically active agent.
2. (Original) The pharmaceutical composition according to claim 1, wherein the composition comprises the botanical extract, and wherein the botanical extract is an extract of Guarana, *Ginkgo biloba*, Kola nut, Goldenseal, Golo Kola, *Schizandra*, Elderberry, St. John's Wort, Valerian and *Ephedra*, black tea, white tea, java tea, garlic oil, fiber, green tea, lemon oil, mace, licorice, onion oil, orange oil, rosemary, milk thistle, *Echinacea*, Siberian ginseng or *Panax ginseng*, lemon balm, *Kava kava*, matte, bilberry, soy, grapefruit, seaweed, hawthorn, lime blossom, sage, clove, basil, curcumin, taurine, wild oat herb, oat grain, dandelion, gentian, aloe vera, hops, cinnamon, peppermint, grape, chamomile, fennel, marshmallow, ginger, slippery elm, cardamon, coriander, anise, thyme, rehmannia, eucalyptus, menthol, schisandra, withania, cowslip, lycium, or passion flower.
3. (Original) The pharmaceutical composition according to claim 2, wherein the botanical extract is an extract of oat grain.

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4. (Withdrawn) The pharmaceutical composition of claim 3, wherein the botanical extract comprises avenanthramide.
5. (Withdrawn) The pharmaceutical composition according to claim 1, wherein the composition comprises the pharmaceutically active agent, and wherein the pharmaceutically active agent is selected from the group consisting of beta-sitosterol, caffeine, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphoraphane, tangeretin, folic acid, and menthol.
6. (Withdrawn) The pharmaceutical composition according to claim 1, wherein the composition comprises the pharmaceutically active agent, and wherein the pharmaceutically active agent is selected from the group consisting of an antihistamine, a decongestant, a corticosteroid, a non-steroidal anti-inflammatory drug, a bronchodilator, a vasodilator, such as nitroglycerin, and a local anaesthetic.
7. (Withdrawn) The pharmaceutical composition of claim 6, wherein the vasodilator is nitroglycerin.
8. (Original) The pharmaceutical composition according to claim 1, wherein the β (1-3) β (1-4) glucan is derived from a cereal grain or a part of the cereal grain.
9. (Original) The pharmaceutical composition according to claim 8, wherein the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.
10. (Canceled)

11. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.

12. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the cereal β -glucan composition has a clarity value of from about 5 to about 100 NTU.

13. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the β (1-3) β (1-4) glucan composition is produced according to a method of isolating a β (1-3) β (1-4) glucan composition from a milled cereal grain or a milled part of the cereal grain, the method comprising:

(i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a value of pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight percent β (1-3) β (1-4) glucan;

(ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 μm from said extract to produce a purified extract comprising β (1-3) β (1-4) glucan having a particle size of equal to or less than 0.2 μm wherein the step of removing particulate material comprises filtering out material having a particle size of greater than about 0.2 μm from said extract by filtration with a cutoff of 0.2 μm to produce the purified extract comprising β (1-3) β (1-4) glucan having a particle size of equal to or less than 0.2 μm as a filtrate;

(iii) adding from about 10% to about 20% (vol/vol) of a C₁-C₄ alcohol to the purified extract to precipitate the β (1-3) β (1-4) glucan composition, and

(iv) isolating the β (1-3) β (1-4) glucan composition.

14. (Previously Presented) The pharmaceutical composition according to claim 13, wherein the alcohol is selected from the group consisting of methanol, ethanol and isopropanol.

15. (Previously Presented) The pharmaceutical composition according to claim 14, wherein the alcohol is ethanol.

16. (Previously Presented) The pharmaceutical composition according to claim 13, wherein said step of removing particulate material in said method further comprises the following steps prior to the step of microfiltration:

one, or more than one step of adding a flocculant, a coagulant or both the flocculant and the coagulant to said extract to coagulate particulate material having a particle size of greater than about 0.2 μm , and removing coagulated material from said extract, and
digesting starch material in said extract.

17. (Original) The pharmaceutical composition according to claim 16, wherein in said step of digesting in said method, said starch material is digested with an enzyme.

18. (Original) The pharmaceutical composition according to claim 17, wherein prior to digesting said starch material, said alkaline solution is neutralized.

19. (Original) The pharmaceutical composition according to claim 18, wherein following the digestion of said starch material in said method, said enzyme is inactivated.

20. (Original) The pharmaceutical composition according to claim 19, wherein said enzyme is inactivated by acidifying the neutralized solution.

21. (Original) The pharmaceutical composition according to claim 17, wherein said enzyme is an amylase.

22. (Original) The pharmaceutical composition according to claim 21, wherein said amylase does not require a calcium cofactor.

23. (Original) The pharmaceutical composition according to claim 13, wherein the cereal is selected from the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, a cultivar of corn, and a mixture thereof.

24. (Previously Presented) The pharmaceutical composition according to claim 13, wherein the pH of the alkaline solution used in said method is from about 9.25 to about 9.75.

25. (Canceled)

26. (Original) The pharmaceutical composition according to claim 13, wherein said step of adding (step iii) in said method is conducted at a temperature of from about 1°C to about 10°C.

27. (Previously Presented) The pharmaceutical composition according to claim 13, wherein said method further comprises one, or more than one step of dissolving the isolated β (1-3) β (1-4) glucan in an aqueous solution, precipitating the β (1-3) β (1-4) glucan by adding about 10% to about 20% (vol/vol) of the C₁-C₄ alcohol to the aqueous solution, and isolating the β (1-3) β (1-4) glucan.

28. (Previously Presented) A pharmaceutical composition consisting essentially of:
a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of equal to or less than 0.2 μ m, less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities,
a botanical extract, or a pharmaceutically active agent, and
a pharmaceutically acceptable diluent or carrier.

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29. (Previously Presented) The pharmaceutical composition according to claim 28, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.

30. (Previously Presented) A pharmaceutical composition consisting of:

a β (1-3) β (1-4) glucan composition consisting essentially of at least about 75% β (1-3) β (1-4) glucan having a particle size of equal to or less than 0.2 μm , less than 10% ash impurities, less than 10% protein impurities and less than 5% lipid impurities,
a botanical extract, or a pharmaceutically active agent, and
a pharmaceutically acceptable diluent or carrier.

31. (Previously Presented) The pharmaceutical composition according to claim 30, wherein the β (1-3) β (1-4) glucan composition has a purity of at least about 92%, and contains less than 3.5% ash impurities, less than 3.5 % protein impurities, and less than 1% lipid impurities.